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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		P21729.02	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]	Application Number		Filed
	10/715,797		11-18-2003
on	First Named Inventor		
Signature	Steve Golden		
	Art Unit		Examiner
Typed or printed name	3773	3	Julian W. Woo
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s).  Note: No more than five (5) pages may be provided.			
I am the	241/2. /.		
applicant/inventor.	<u> </u>	1/1/100	ALA) Signature
assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	<u>Katrina A. Witschen</u> Typed or printed name		
attorney or agent of record. 59,862 Registration number	763-505-8418 Telephone number		
attorney or agent acting under 37 CFR 1.34.	7	Narch I	2 2008
Registration number if acting under 37 CFR 1.34			Date
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  Submit multiple forms if more than one signature is required, see below*.			
*Total of forms are submitted			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Steve Golden et. al Examiner: Julian W. Woo

Serial No.: 10/715,797 Group Art Unit: 3773

Filing Date: 11-18-2003 Docket No.: P21729.02

Title: APPARATUS AND METHODS FOR ANASTOMOSIS

## **MS After Final**

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

## PRE-APPEAL BRIEF REQUEST FOR REVIEW--ARGUMENTS

Applicants request review of the final rejection of claims 64, 66-75, 124-127, 129-132, 135-137 and 139-141 in the above-identified application. These claims, as they appear in the Listing of the Claims on pages 2-7 of the Amendment and Response filed August 20, 2007 were rejected in the Final Office Action mailed November 14, 2007.

Claims 64, 124, 125, 127 and 129-131 were rejected under 35 U.S.C. 102(e) as being anticipated by Swanson *et al* (US 6,113,612). In the Final Office Action at page 2 it was advanced, "Swanson *et al* disclose, at least in figures 7-11 and in col. 6, line 28 to col. 7, line 34, lines 31-45; a method for performing an anastomosis on a vessel wall, while maintaining blood flow within the vessel, where the method includes positioning a cannula (110)...the cannula or tubular member being introduced (i.e., inserted) or delivered into the vessel wall from the interior of the vessel". This rejection is respectfully traversed.

Claim 64 recites "the cannula is introduced into the vessel wall from the interior of the vessel" and this is not disclosed or suggested in Swanson *et al*. The previous Office Action dated April 19, 2007 stated at page 3 that tube 240 of Swanson *et al* is positioned in the vessel wall from the interior of the vessel using guidewire 210, which is in the interior of the vessel. Applicants argued in a response dated August 20, 2007 that

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Title: Apparatus and Methods for Anastomosis

Swanson *et al* does not introduce tube 240 into a vessel wall from the interior of the vessel as set forth in amended claim 64. (Applicants' Amendment and Response After Non-Final Rejection p. 9). In response, the Final Rejection at p. 7 stated, "Swanson *et al* indeed disclose a cannula (110)...."

It is respectfully submitted that this substantively changes the rejection of claim 64 in that the Final Rejection is reading the reference in a different fashion than the original Office Action. In the first Office Action of April 19, 2007 at page 3, the Examiner posits that the cannula is element 240, the tube, of Swanson *et al*. Whereas in the Final Office Action at page 2, the Examiner references element 110, the balloon, of Swanson *et al* as being the purported cannula. Applicants were not given a chance to respond to this substantively changed rejection prior to it being made final. As a result, it was improper to make this rejection final. Further, component 110 of Swanson *et al* is a balloon. It is not a cannula as alleged in the Final Rejection. Regardless, neither the tube 240 nor the balloon 110 of Swanson *et al* is disclosed as being introduced into the vessel wall *from the interior of the vessel*. Swanson *et al* do not disclose a cannula being introduced into a vessel from the interior of the vessel and no citation was provided in support of the notion that Swanson *et al* so disclose the claimed invention.

Likewise, Claim 127 sets forth "passing the first end of the tubular member from the interior of the vessel through the vessel wall at a first vessel wall location..." It is respectfully submitted that Swanson *et al* do not disclose this step. If the Examiner disagrees, the Applicants respectfully request clarification as to how this disclosure is being read on claim 127. Accordingly, reconsideration and withdrawal of the rejection under Swanson *et al* is requested.

Claims 66-74, 126, 132, 135-137 and 139-141 were rejected under 35 U.S.C. § 102(e) as being anticipated by LeMole (U.S. Patent No. 5,893,369). Claim 66 recites in part "anastomosing a graft to the vessel at the opening". In contrast, LeMole attaches

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graft 14 to vessel 12 <u>before</u> forming an opening in the vessel (see, e.g., column 5, line 34-column 6, line 36). Therefore, LeMole does not disclose or suggest the method claimed in claim 66. The Final Rejection stated at p. 7, "LeMole indeed discloses forming an opening in the vessel wall before and during anastomosing a graft to the vessel at the opening. That is, forming the opening complete the anastomosing process by forming a flow path between the graft and the vessel." However, no citation to LeMole was set forth in support of this argument. Indeed, LeMole does not disclose forming an opening prior to anastomosing a graft to a vessel. The Final Rejection argument ignores that claim 66 recites "a method for performing an anastomosis ... while maintaining blood flow within the vessel ...." LeMole cannot both form a flow path and also maintain blood flow through that path. A blood flow path must be created prior to the maintaining of blood flow through that path. As a result, the rejection is not clear. Accordingly, reconsideration and withdrawal of the rejections based on LeMole are requested.

Claim 75 was rejected under 35 U.S.C. § 103(a) as being unpatentable over LeMole in view of Ho *et al* (U.S. Patent No. 6,514, 265). As advanced by the Examiner in the Final Office Action, "Ho et al. teach...fastening the walls of a graft and a vessel together using self-closing fasteners 210. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ho et al., to modify the method of LeMole, so that self-closing fasteners are applied for the fastening of a graft to a vessel." Claim 75 indirectly depends from claim 66. Ho *et al* is not presented as an attempt to make up for the deficiencies in the LeMole rejection noted above in connection with claim 66. Indeed, Ho *et al* do not make up for the deficiencies in LeMole as explained above therefore a prima facie case of obviousness has not been established. Accordingly, reconsideration and withdrawal of the rejection based on LeMole in view of Ho *et al* is requested.

## ARGUMENTS ACCOMPANYING PRE-APPEAL BRIEF REQUEST FOR REVIEW

Serial No. 10/715,797

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Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (763) 505-8418 to facilitate prosecution of this application.

A Notice of Appeal accompanies this Pre-Appeal Brief Request for Review. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

Date: March / 2008

Respectfully submitted,

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